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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,166	04/26/2001	Edward W. Merrill	37697-0035	7738

26633 7590 01/30/2003

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,166

Applicant(s)

MERRILL ET AL.

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-149 is/are pending in the application.
- 4a) Of the above claim(s) 137-149 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-136 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1, claims 124-136 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that no serious burden exists on the examiner to search all claims because examiner had already searched all claims. This is not found persuasive because examiner attempted to search all claims and in doing so, realized that the claimed invention had many different claimed groups, in which each group fell into a different class of art, in arts unfamiliar to the examiner. These non-elected groups were originally restricted in efforts to offer a fair examination of the non-elected claims in the future, wherein a fair examination is given when searched in the appropriate class of art. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statement filed September 20, 2002 contains dash marks through multiple references listed, due to previous citations by the examiner. The references have already been considered and were dashed in order to avoid duplicate citations.

Response to Arguments

3. Applicant's arguments filed September 18, 2002 have been fully considered but they are not persuasive. Referring to applicant's argument for the Hyon in view of Howard and in further view of Bashir rejections, applicant has not claimed how the melting melts are produced, applicant simply claims that multiple melting peaks are present. Therefore, method of producing multiple melting peaks disclosed by Howard and Bashir still read on the applicant's claims. Applicant also argues that production of multiple melting peaks by Howard produces increased crystallinity, however, applicant does not claim any specific crystallinity effects in the independent claims.

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Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 124-127, 129-130, and 132-135 are rejected under 35 U.S.C. 102(e) as being anticipated by McKellop et al. (USPN 6,165,220, cited by applicant in IDS). Referring to claims 124 and 132, McKellop discloses a medical prosthesis or a material (col.1, lines 14-16), being formed of radiation treated UHMWPE having cross-links (fig.1; col.2, lines 20-27) and multiple melting peaks (fig.3, 14, 15; col.12, lines 37-50).

Referring to claims 125, 126, 133, and 134, McKellop discloses an UHMWPE having two or three melting peaks (figs.3, 14, 15).

Referring to claims 127 and 135, McKellop discloses UHMWPE subjected to irradiation (fig.1; col.11, lines 58-59; col.3, lines 56-65).

Referring to claim 129, McKellop discloses an UHMWPE having an initial average molecular weight of greater than about 1 million (col.5, lines 40-47).

Referring to claim 130, McKellop discloses a medical prosthesis arranged for joint replacement (col.5, line 66-col.6, line 22).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 124, 127-132, and 135-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saum et al. (USPN 6,017,975, cited by applicant in IDS) in view of Lemstra (USPN 5,066,755, cited by applicant in IDS). Referring to claims 124 and 132, Saum disclose a medical prosthesis or material substantially as claimed (col.1, lines 13-16). Saum discloses a radiation treated UHMWPE having cross-links (col.2, lines 48-51). Saum does not disclose however, UHMWPE having multiple melting peaks. Lemstra teaches in the polymer art, irradiation of polyethylene causes formation of multiple melting peaks, which optimizes the thermal and mechanical/chemical properties of the material (col.21, lines 7-20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Lemstra's teaching of irradiation to form multiple melting peaks, with Saum's disclosed irradiated UHMWPE, and from that conclude that since Saum's material has been irradiated, it may have multiple melting peaks, or may be irradiated according to Lemstra's protocol to form multiple melting peaks, in order to optimize thermal and mechanical properties.

Referring to claims 127 and 135, Saum discloses heating UHMWPE by irradiation (col.2, lines 50-51).

Referring to claim 129, Saum discloses an UHMWPE having an initial average molecular weight of greater than about 1 million (col.3, lines 20-24, 55-67; col.4, lines 1-9).

Referring to claim 130, Saum discloses a medical prosthesis arranged for joint replacement (col.5, lines 62-68).

Referring to claims 131 and 136, Saum discloses a structure having less than about 50% crystallinity (table 5,) and less than about 940Mpa tensile elastic modulus (tables 1-5).

Referring to claim 128, Saum discloses cross-linking UHMWPE (tables 1-5), however does not disclose testing dissolution point in xylene or decalin. Lemstra teaches cross-linking UHMWPE (at the

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same dosage; col.11, lines 8-10) and testing the material in decalin or xylene, wherein dissolution temperature is below 240°C (col.10, lines 7-20), therefore; the cross-linked UHMWPE will not dissolve in xylene or decalin at the claimed temperature of 130°C and 150°C respectively, due to the extensive cross-linkage. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Lemstra's teaching of dissolution temperatures in xylene and decalin for cross-linked UHMWPE by irradiation, with the irradiated cross-linked UHMWPE of Saum, in order conclude that since the Lemstra's irradiation dosage was the same as Saum's irradiation dosage for cross-linking polyethylene, the same cross-linkage would occur in both Saum's and Lemstra's polyethylene and dissolution would not occur at the claimed temperatures in the Saum polyethylene since they do not occur at the Lemstra polyethylene.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on September 20, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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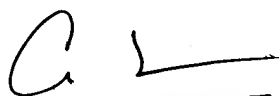
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Cheryl Miller

January 23, 2003


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700